REMARKS

Reconsideration of the above-identified application is respectfully requested. Claims 1, 2, 6, 7, 9, 10, 11, 12, 13, 19, 29, and 30 have been amended, Claim 22 has been canceled, and new Claim 32 has been added. Thus, Claims 1-21, and 23-32 are pending in the present application. Applicants acknowledge with appreciation the allowable subject matter of Claims 4, 5, 16, 18, and 23-31.

Claims 1-31 were rejected in the August 1, 2002 Office Action (hereinafter "Office Action") under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-25 of U.S. Patent No. 6,096,054, issued to Wyzgala et al. Claims 1, 2, 6, 9, 11-13, and 19 were further rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,376,100, issued to Lefebvre (hereinafter "Lefebvre"). Claims 1, 2, 9, 14, 15, and 17 were further rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,465,072, issued to Taheri (hereinafter "Taheri"), in view of U.S. Patent No. 5,897,566, issued to Shturman et al. (hereinafter "Shturman et al."). Claims 3 and 10 were further rejected under 35 U.S.C. § 103(a) as being unpatentable over Taheri and Shturman et al. in further view of U.S. Patent No. 4,706,670 issued to Andersen et al. (hereinafter "Andersen et al."). Claims 7 and 8 were further rejected under 35 U.S.C. § 103(a) as being unpatentable over Lefebvre in view of U.S. Patent No. 5,318,576, issued to Plassche, Jr. et al. (hereinafter "Plassche, Jr. et al."). Lastly, Claims 20-22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lefebvre in view of U.S. Patent No. 5,250,060, issued to Carbo et al. (hereinafter "Carbo et al."). Claims 29 and 30 were further rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. For the reasons as will be discussed in more detail below, applicants respectfully assert the claims of the present application are in condition for allowance.

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Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 29 and 30 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Specifically, in Claim 29, line 1, the Office Action states there is no antecedent basis for the phrase "the reverse pull-back device," and in lines 1-2, there is no antecedent basis for "the polymeric balloon section." The Office Action further states that in Claim 30, line 1, there is no antecedent basis for "the reverse pull-back device," and in line 2, the Office Action states there is no antecedent basis for "the wire mesh." Applicants have amended Claims 29 and 30 to depend from Claims 28 and 29, respectively, to overcome the rejections stated in the Office Action with regard to 35 U.S.C. § 112, second paragraph. Accordingly, applicants respectfully request the withdrawal of the pending rejections under 35 U.S.C. § 112, second paragraph, with regard to Claims 29 and 30.

Rejections Under Obviousness-Type Double Patenting

Claims 1-31 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-25 of U.S. Patent No. 6,096,054. The Office Action states that although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of U.S. Patent No. 6,096,054 set forth the currently claimed subject matter of the present application. Without agreeing to the rejection but to further prosecution, applicants are submitting herewith a terminal disclaimer to obviate the double patenting rejection over U.S. Patent No. 6,096,054.

Rejections Under 35 U.S.C. § 102(b)

Claims 1, 2, 6, 9, 11-13, and 19 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Lefebvre. Applicants respectfully traverse the rejection of these claims. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or

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inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q. 2d 1051, 1053 (Fed. Cir. 1987). For the following reasons, applicants assert that Lefebvre fails to teach or suggest each and every element of the rejected claims.

Independent Claim 1

As amended, Claim 1 recites a device for ablating an occlusion in a patient's blood vessel that includes a drive shaft adapted to be connected to a rotational driving source; and an ablation burr secured to the drive shaft for rotation therewith. The ablation burr comprises a polymeric balloon section being expandable from an unexpanded state with a first diameter to an expanded state with a second larger diameter, and further having an abrasive coating disposed on at least a portion of its exterior surface to ablate an occlusion in a patient's vessel. The device further includes an expansion control system to control the expansion of the burr to a predetermined expanded diameter when in the expanded state. As will be discussed in more detail below, Lefebvre fails to teach or suggest the novel combination of features recited in amended Claim 1, including an ablation burr comprising a polymeric balloon section.

Lefebvre purportedly discloses a rotary atherectomy device that comprises a plastic conduit 2 of which slits 4 are provided over a part of its length and longitudinally. The proximal end of the conduit 2 is coupled to a rotational drive source so that the conduit can expand via rotation to an expanded diameter due to the slits 4. Column 4, lines 27-40. In contrast to the teachings of Lefebvre, the present invention recites a polymeric balloon section, and thus, has a contiguous or uninterrupted outer surface that is capable of being inflated during use. Thus, applicants respectfully assert that the structure of the recited balloon section is quite different from the conduit taught by Lefebvre. Therefore, for at least this reason, Lefebvre fails to teach or suggest each and every element of amended Claim 1. Accordingly, applicants respectfully

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request the withdrawal of the pending rejection under Section 102(b) with regard to Claim 1. Furthermore, applicants respectfully request that the Examiner also withdraw the pending rejections to Claims 2, 6, 9, and 10, which depend from allowable Claim 1.

Independent Claim 11

As amended, Claim 11 recites a device for ablating an occlusion in a patient's blood vessel comprising a drive shaft, and an ablation burr secured to the drive shaft. The burr includes a nose section having a fixed maximum diameter and an expandable polymeric balloon section having an abrasive disposed on at least a portion thereof. The polymeric balloon section has a diameter that increases as the rotational speed of the drive shaft increases, wherein the polymeric balloon section includes a system that limits the expansion of the burr to a predetermined maximum diameter. For the same reason as discussed above with regard to Claim 1, Lefebvre fails to teach or suggest an ablation burr having a polymeric balloon section. Thus, for at least this reason, applicants respectfully request the withdrawal of the § 102 rejection with regard to Claim 11. Accordingly, applicants respectfully request that the Examiner also withdraw the pending rejections to Claims 12 and 13, which depend from allowable Claim 11.

Independent Claim 19

As amended, Claim 19 recites a method for ablating a lesion or occlusion in a patient's vessel or stent. The method includes routing an ablation burr in an unexpanded state over a guide wire to a position distal to the lesion; rotating a drive shaft to begin the expansion of the ablation bur; creating a seal between the vessel or stent and the ablation burr by expanding the ablation burr to an expanded state; pulling the ablation burr in an expanded state proximally toward to the lesion; and ablating the lesion with the ablation burr as the ablation burr passes through the lesion. As will be discussed in more detail below, Lefebvre fails to teach or suggest

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the novel combination of features recited in Claim 19, including "creating a seal between the vessel or stent and the ablation burr by expanding the ablation burr to an expanded state."

As was discussed above, Lefebvre purportedly teaches a rotary atherectomy device that comprises a plastic conduit 2 of which slits 4 are provided over a part of its length and longitudinally. The proximal end of the conduit 2 is coupled to a rotational drive source so that the conduit can expand via rotation to an expanded diameter due to the slits 4. Column 4, lines 27-40. However, Lefebvre does not teach or suggest creating a seal between the vessel and the conduit when expanded. In contrast, the present invention, as defined by Claim 19, creates a seal between the vessel or stent and the ablation burr by expanding the ablation burr to an expanded state. Therefore, for at least this reason, applicants assert that Lefebvre fails to teach or suggest each and every element of Claim 19. Thus, applicants respectfully request the withdrawal of the pending rejection under Section 102(b) with regard to Claim 19. Accordingly, applicants respectfully request the Examiner also withdraw the pending rejections to Claims 20 and 21, which depend from allowable Claim 1.

Rejections Under 35 U.S.C. § 103(a)

Claims 1, 2, 9, 14, 15, and 17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Taheri in view of Shturman et al. Claims 3 and 10 were further rejected under 35 U.S.C. § 103(a) as being unpatentable over Taheri and Shturman et al. in further view of Andersen et al. Claims 7 and 8 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lefebvre in view of Plassche, Jr. et al. Lastly, Claims 20-22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lefebvre in view of Carbo et al. Applicants respectfully traverse the rejections of these claims.

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Independent Claim 1

As amended, Claim 1 recites a device for ablating an occlusion in a patient's blood vessel that includes a drive shaft adapted to be connected to a rotational driving source, and an ablation burr secured to the drive shaft for rotation therewith. The ablation burr comprises a polymeric balloon section being expandable from an unexpanded state with a first diameter to an expanded state with a second larger diameter, and further having an abrasive coating disposed on at least a portion of its exterior surface to ablate an occlusion in a patient's vessel. The device further includes an expansion control system to control the expansion of the burr to a predetermined expanded diameter when in the expanded state. As will be discussed in more detail below, Taheri and Shturman et al. both fail to teach or suggest, either alone or in combination, the novel combination of amended Claim 1, including a drive shaft adapted to be connected to a rotational driving source, and an ablation burr secured to the drive shaft for rotation therewith.

The Office Action states that Taheri discloses a device for removing occlusions within a patient's blood vessel comprising a drive shaft 12 and an ablation burr 13 secured to the drive shaft wherein the burr 13 is comprised of a polymeric material in the shape of a tube which is expanded from a first to a second larger diameter. The expandable polymeric burr includes a plurality of outwardly-extending abrasive burr-like pips or ribs on its outer surface for scraping the walls of the blood vessel, but does not disclose an abrasive coating disposed on at least a portion of the polymeric tube section. However, the Office contends that one of ordinary skill in the art would have readily appreciated that a conventional abrasive coating could have been applied in place of the abrasive pips disclosed by Taheri as an obvious substitution of conventional abrasives. The Office also contends the substitution is particularly obvious in view of Shturman et al., which discloses the use of an abrasive coating on a burr for removing deposits within a patient's blood vessel. Therefore, the Office contends that to have used an abrasive

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coating on the polymeric burr of Taheri rather than the disclosed abrasive pips would have been obvious to one of ordinary skill in the art in view of the teachings of Shturman.

Applicants agree with the Office Action that Taheri fails to teach or suggest an abrasive coating disposed on at least a portion of the polymeric tube section. However, applicants respectfully assert that Taheri fails to teach or suggest the novel combination of features set forth in amended Claim 1, including a drive shaft adapted to be connected to a rotational driving source, and an ablation burr secured to the drive shaft for rotation therewith.

Taheri purportedly discloses a catheter 10 which includes a needle 11, a sleeve 12, a balloon 12 and a syringe 14. The needle 11 is an elongated cylindrical rod having its forward end sharpened. The sleeve 12 is an elongated tubular member mounted to an intermediate portion of the needle. The sleeve is mounted on the needle against either axial or rotational movement relative to the needle. Column 2, lines 45-54. The balloon 13 is arranged within an annular recess 24 formed in the sleeve's outer surface 21. The ends of the balloon 13 are glued or otherwise secured to the recess surface 25, thereby forming an annular sealed chamber 32. The fluid to either inflate or deflate the balloon 13 may be selectively supplied to or withdrawn from the chamber 32 by the syringe 14 through internal passageway 33. Column 2, line 61 through column 3, line 3. Thus, the sleeve, and therefore, the inflatable balloon does not rotate relative to the needle.

In contrast to the teachings of Taheri, one embodiment of the present invention, as defined by Claim 1, includes a drive shaft adapted to be connected to a rotational driving source, and an ablation burr secured to the drive shaft for rotation therewith. As indicated above, the sleeve of the Taheri device to which the balloon is secured is prevented from either axial or rotational movement relative to the needle. Therefore, applicants respectfully assert that Taheri fails to teach or suggest "a drive shaft adapted to be connected to a rotational driving source; and

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an ablation burr secured to the drive shaft for rotation therewith." Moreover, a suggested modification of the sleeve of Taheri to rotate relative to the needle is in direct contrast to the explicit teaching that the balloon is to resist axial or rotational movement with respect to the needle. Accordingly, Taheri is not properly combinable with any reference teaching "a drive shaft adapted to be connected to a rotational driving source; and an ablation burr secured to the drive shaft for rotation therewith."

Under Section 103, a *prima facie* case of obviousness is established only if the cited references, alone or in combination, teach or suggest each of the limitations of a recited claim. *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993). As applied to Claim 1 of the present application, the cited reference, Taheri fails to teach or suggest a "a drive shaft adapted to be connected to a rotational driving source; and an ablation burr secured to the drive shaft for rotation therewith." Furthermore, applicants respectfully assert that Taheri cannot be properly combined to include a "drive shaft adapted to be connected to a rotational driving source; and an ablation burr secured to the drive shaft for rotation therewith." Applicants assert that the Office has failed to make a *prima facie* case of obviousness, and therefore, respectfully request the withdrawal of the § 103 rejection with regard to Claim 1. Accordingly, applicants further request the Examiner also withdraw the pending rejection to Claims 2 and 9, which depend from allowable Claim 1.

Independent Claim 14

Claim 14 recites a reverse pull-back device for ablating a lesion in a patient's blood vessel or stent. The reverse pull-back device includes a drive shaft, and an ablation burr secured to the drive shaft. The ablation burr comprises a polymeric balloon section having an unexpanded state with a first diameter and an expanded state with a second larger diameter. The polymeric balloon section has an abrasive coating disposed on at least a portion of its exterior surface to

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ablate a lesion in a patient's vessel or stent, wherein the balloon section is expandable to create a seal with the vessel or stent when in the expanded state.

As was discussed above, Taheri purportedly discloses a catheter 10 which includes a needle 11, a sleeve 12, a balloon 12 and a syringe 14. The sleeve 12 is an elongated tubular member mounted on the needle 11 against either axial or rotational movement relative to the needle 11. Column 2, lines 45-54. The balloon 13 is arranged within an annular recess 24 formed in the sleeve's outer surface 21. The ends of the balloon 13 are glued or otherwise secured to the recess surface 25, thereby forming an annular sealed chamber 32. The fluid to either inflate or deflate the balloon 13 may be selectively supplied to or withdrawn from the chamber 32 by the syringe 14 through internal passageway 33. Column 2, line 61 through column 3, line 3. However, Taheri does not teach or suggest "wherein the balloon section is expandable to create a seal with the vessel or stent when in the expanded state."

Shturmann et al. purportedly teaches a rotational atherectomy device composed of a handle portion 10, an elongated, flexible drive shaft 20 having an enlarged diameter tissue removal section 28, and an elongated catheter 13 extending distally from the handle portion 10. Column 5, lines 61-65. However, Shturmann et al. does not teach or suggest a balloon section that is expandable to create a seal with the vessel or stent when in the expanded state.

In contrast, the present invention, as defined by Claim 14, creates a seal between the vessel or stent and the balloon section in the expanded state. Therefore, for at least this reason, applicants assert that both Taheri and Shturmann et al. fail to teach or suggest each and every element of Claim 14. Thus, applicants respectfully request the withdrawal of the pending rejection under Section 102(b) with regard to Claim 14. Accordingly, applicants respectfully request that the Examiner also withdraw the pending rejections to Claims 15 and 17, which depend from allowable Claim 14.

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Dependent Claims 3 and 10

Claims 3 and 10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Taheri and Shturman et al. in further view of Andersen et al. Dependent Claims 3 and 10 depend from allowable Claim 1, and as such, contain all of the elements of allowable Claim 1. Accordingly, for the reasons discussed above with respect to amended Claim 1, Claims 3 and 10 are allowable over the cited and applied references. Thus, Applicants respectfully request withdrawal of the pending rejection under 35 U.S.C. § 103(a) with regard to Claims 3 and 10.

Dependent Claims 7 and 8

Claims 7 and 8 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lefebvre in view of Plassche, Jr. et al. Dependent Claims 7 and 8 depend from allowable Claim 1, and as such, contain all of the elements of allowable Claim 1. Accordingly, for at least the reasons discussed above with respect to amended Claim 1, Claims 7 and 8 are allowable over the cited and applied references. Thus, Applicants respectfully request withdrawal of the pending rejection under 35 U.S.C. § 103(a) with regard to Claims 7 and 8.

Dependent Claims 20-22

Claims 20-22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lefebvre in view of Carbo et al. Claim 22 has been canceled, thereby rendering the rejection to this claim moot. Dependent Claims 20 and 21 depend from allowable Claim 19, and as such, contain all of the elements of allowable Claim 19. Accordingly, for at least the reasons discussed above with respect to amended Claim 19, Claims 20 and 21 are allowable over the cited and applied references. Thus, Applicants respectfully request withdrawal of the pending rejection under 35 U.S.C. § 103(a) with regard to Claims 20 and 21.

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CONCLUSION

Applicants assert the claims of the present application are allowable over the cited and applied references. If any further questions remain, the Examiner is invited to telephone applicants' attorney at the number listed below.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the U.S. Postal Service in a sealed envelope as first class mail with postage thereon fully prepaid and addressed to the U.S. Patent and Trademark Office, P.O. Box 2327, Arlington, VA 22202, on the below date.

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VERSION WITH MARKINGS TO SHOW CHANGES MADE JANUARY 2, 2003

In the Claims:

1. (Amended) A device for ablating an occlusion in a patient's blood vessel, comprising:

a drive shaft adapted to be connected to a rotational driving source;

an ablation burr secured to the drive shaft for rotation therewith, the ablation burr comprising a polymeric [tube] balloon section, the polymeric [tube] balloon section being expandable from an unexpanded state with a first diameter to an expanded state with a second larger diameter, the polymeric [tube] balloon section having an abrasive coating disposed on at least a portion of its exterior surface to ablate an occlusion in a patient's vessel; and

an expansion control system to control the expansion of the burr to a predetermined expanded diameter when in the expanded state.

1. (Amended) The device of Claim 1, wherein the expansion control system is embedded within the polymeric [tube] balloon section.

2. (Amended) The device of Claim 1, wherein the polymeric [tube] balloon section assumes the expanded state when rotated by the drive shaft.

3. (Amended) The device of Claim 1, wherein the expansion control system comprises internal curvilinear ribs disposed on the inside surface of the polymeric [tube] balloon section.

4. (Amended) The atherectomy device of Claim 1, wherein the polymeric [tube] balloon section is post cross-linked, the post cross-linked polymeric [tube] balloon section functioning as the expansion control system of the atherectomy device.

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5. (Amended) The device of Claim 1, wherein the expansion control system comprises a first layer of fiber within the polymeric [tube] balloon section disposed in a first direction, and a second layer of fiber within the polymeric [tube] balloon section disposed in a second direction that is opposite of the first direction.

11. (Amended) [An] A device for ablating an occlusion in a patient's blood vessel, comprising:

a drive shaft;

an ablation burr secured to the drive shaft, the burr including a nose section having a fixed maximum diameter and an expandable polymeric balloon section having an abrasive disposed on at least a portion thereof, the polymeric balloon section having a diameter that increases as the rotational speed of the drive shaft increases;

wherein the polymeric balloon section includes a system that limits the expansion of the burr to a predetermined maximum diameter.

12. (Amended) The atherectomy device of Claim 11, wherein the nose section of the ablation burr having a maximum diameter includes a stepped portion disposed at the proximal end of the nose section and having a substantially constant diameter that is smaller than the maximum diameter of the nose section, and wherein the polymeric balloon section comprises a tube disposed over the stepped portion of the nose section.

13. (Amended) The atherectomy device of claim 12, wherein the ablation burr further includes an end section having a fixed maximum diameter, the end section of the ablation burr includes a stepped portion disposed at the distal end of the end section and having a substantially constant diameter that is smaller than the maximum diameter of the end section, the polymeric [tube] balloon section disposed over the stepped portion of the end section.

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19. (Amended) A method for ablating a lesion or occlusion in a patient's vessel or stent comprising:

routing an ablation burr in an unexpanded state over a guide wire to a position distal to the lesion;

rotating a drive shaft to begin the expansion of the ablation bur;

creating a seal between the vessel or stent and the ablation burr by expanding the ablation burr to an expanded state;

pulling the ablation burr in an expanded state proximally toward to the lesion; and

ablating the lesion with the ablation burr as the ablation burr passes through the lesion.

29. The reverse pull-back device according to Claim [8] 28, wherein the polymeric balloon section has a distal end portion and a proximal end portion and includes a wire mesh disposed within the polymeric balloon section, the wire mesh beginning at the proximal end portion of the balloon section and extending to about the midpoint of the ablation burr so that the proximal end portion of the balloon section forms a concave shaped portion in the expanded state.

30. The reverse pull-back device according to Claim [9] 29, wherein the abrasive is coated on the wire mesh in the expanded state.

New Claim 32 has been added.

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